

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA,

Plaintiff,

vs.

DOLORES LOVIN (5); MARY
ARONSON (6); CHANDRESH B. SHAH,
M.D. (8); RICHARD EDWARD KOCH (11);
PHILIP JAMES BIDWELL (12); JEFFREY
A. LIGHT (14); TRACY O'NEAL
TYLER (15); PETER P. BRAGANSA (16),

Defendant.

CASE NO. 07cr2016-IEG

Order Denying Motions to Dismiss
[Doc. Nos. 313, 321, 327, 317 & 319]

Presently before the Court are the following motions: Defendant Philip James Bidwell's motion to dismiss the indictment [Doc. 313]; Defendant Jeffrey A. Light's motion to dismiss the indictment [Doc. No. 321]; Defendants Dolores Lovin and Mary Aronson's motion to dismiss the indictment [Doc. No. 327]; and Defendants Tracy O'Neal Tyler, Philip James Bidwell, and Jeffrey Light's motion to dismiss Counts 1 and 2 [Doc. Nos. 317 and 319]. All Defendants have joined in the other parties' motions [Doc. Nos. 324, 325, 328, 331, 332, 334, and 363]. The parties filed written oppositions and replies.

A hearing was held before Chief Judge Irma E. Gonzalez on Friday, September 5, 2008. For the reasons set forth herein, the Court DENIES each of Defendants' motions to dismiss.

Background

On July 27, 2007, the Grand Jury returned a 313-count, 124-page indictment in this case. The indictment names eighteen individual defendants and charges them with violations of 18 U.S.C. § 1962(d) (Racketeering Conspiracy), 18 U.S.C. § 1962(c) (Racketeering), 21 U.S.C. § 846 (Conspiracy to Distribute Controlled Substances), 21 U.S.C. § 841(a)(1) (Distribution of Controlled Substances), 18 U.S.C. § 1349 (Conspiracy to Commit Wire and Mail Fraud), 18 U.S.C. § 1343 (Wire Fraud), 18 U.S.C. § 1341 (Mail Fraud), 18 U.S.C. § 1956(h) (Conspiracy to Commit Money Laundering), and 21 U.S.C. § 331 (Distribution of Misbranded Drugs).¹ The indictment also includes three criminal forfeiture allegations under 18 U.S.C. § 982.

The indictment's allegations target a network of businesses, individuals and websites that marketed prescription drugs over the Internet between August 2004 and June 2006. The indictment targets Affpower, an enterprise with its administrative headquarters located in San Jose, Costa Rica, and those affiliated with Affpower. According to the indictment, customers who wished to purchase pharmaceuticals over the Internet, but who did not have a prescription from a personal physician, could visit a website whose owner was affiliated with Affpower. These affiliate marketing websites listed drugs and dosages sold by Affpower and their respective prices. Once a customer clicked on a link corresponding to a particular drug and dosage in order to purchase the drug, the customer was immediately transferred to a different "merchant" website. At the merchant website, the customer entered personal information, including name, date of birth, shipping address, and a credit card number for billing. The customer also filled out an Affpower health questionnaire.

After the customer completed his or her order at the merchant website, doctors participating in the Affpower enterprise accessed the customer orders and questionnaires on the merchant website. Once a doctor approved a pharmaceutical order, the order and an electronic prescription were sent to a pharmacy queue on the merchant website. Thereafter, pharmacies participating in the Affpower enterprise accessed orders and the electronic prescriptions at the merchant websites and shipped the pharmaceuticals to customers.

¹The indictment does not charge all Defendants with violating each criminal statute.

1 The indictment includes allegations against several categories of individuals including
 2 those directly involved in Affpower's operation, licensed pharmacists, licensed medical doctors,
 3 and Affpower affiliates who operated affiliate websites. Prior to the hearing on these motions,
 4 nine of the charged Defendants entered guilty pleas. Two Defendants have not yet appeared
 5 before the Court. The remaining Defendants are now before the Court on these motions.
 6 Defendants Dolores Lovin and Mary Aronson are licensed pharmacists working in the St. Vrain
 7 Pharmacy in Colorado. Defendants Richard Koch, Philip Bidwell, Jeffrey Light, Peter Bragsana
 8 and Tracy Tyler operated multiple affiliate marketing websites, directing customers to Affpower.
 9 The Indictment alleges Philip Bidwell also recruited other affiliates to the Affpower enterprise and
 10 managed those affiliates.

11 *Motions to Dismiss Based Upon Violation of Due Process*

12 Defendants move to dismiss the indictment under the due process clause of the Fifth²
 13 Amendment arguing the Controlled Substances Act ("CSA") is unconstitutionally vague as
 14 applied to this prosecution. Defendants argue due process prohibits the filing of criminal charges
 15 based upon novel theories of prosecution lacking in clear precedent. Defendants argue the legality
 16 of Internet pharmaceutical sales of the type alleged in this case was unsettled at the time of the acts
 17 charged in the Indictment. Defendants argue neither the statute nor judicial decisions gave them
 18 fair notice they could be subject to criminal liability for their actions. Finally, Defendants argue
 19 recent attempts to amend the CSA demonstrate the law as currently written does not prohibit the
 20 conduct alleged in the indictment. Defendants argue all of the Counts in the Indictment are based
 21 upon the alleged CSA violation, and as a result Defendants seek dismissal of the entire Indictment.

22 *1. The Controlled Substances Act*

23 The CSA governs all distribution of controlled substances in the United States. The
 24 government has charged all defendants with illegal distribution and conspiracy to distribute
 25 controlled substances in violation of 21 U.S.C. §§ 841 and 846. Pursuant to § 841(a)(1), it is
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27 ²Defendant Light's motion cites specifically to the Fourteenth Amendment which does not
 28 apply in this federal prosecution. Dusenbury v. United States, 534 U.S. 161, 167 (2002). The
 standard for judging whether a statute is so impermissibly vague as to violate due process is the same
 under both the Fifth and Fourteenth Amendments. Colautti v. Franklin, 439 U.S. 379, 390 (1979);

1 unlawful “for any person knowingly or intentionally to ... distribute, or dispense ... a controlled
 2 substance.” The CSA provides a limited exception in § 822 by authorizing individuals who have
 3 registered with the Attorney General to distribute controlled substances “to the extent authorized
 4 by their registration and in conformity with the other provisions of this subchapter.”

5 The Attorney General has promulgated 21 C.F.R. § 1306.04 which provides as follows:

6 (a) A prescription for a controlled substance to be effective must be issued for a
 7 legitimate medical purpose by an individual practitioner acting in the usual course
 of his professional practice.

8 A person who distributes a controlled substance other than pursuant to a prescription written “for a
 9 legitimate medical purpose by an individual practitioner acting in the usual course of his
 10 professional practice,” violates § 841. United States v. Moore, 423 U.S. 122, 139-40 (1975).

11 2. Proposed Amendment of the CSA

12 On April 1, 2008, the United States Senate passed the Ryan Haight Online Pharmacy
 13 Consumer Protection Act of 2008 to specifically address Internet pharmaceutical sales³. [Philip
 14 Bidwell’s Motion to Dismiss, Doc. No. 313, Attachment A.] The Act would amend the CSA in
 15 several ways as follows:

16 (1) the Act would amend the CSA to define a “valid prescription for controlled
 17 substances dispensed by means of the internet” as one based on “at least one in-person
 18 medical evaluation of the patient” [Attachment A, p.2];

19 (2) the Act would make it unlawful to “fill a prescription for a controlled substance
 20 based solely on a consumer’s completion of an online medical questionnaire,” the
 21 particular conduct referenced in the Indictment in this case [Attachment A, p. 12];

22 (3) the Act would make any violation of the CSA, if committed by doctors or
 23 pharmacists, punishable under the current penalty provisions of § 841 [Attachment A,
 24 p. 13]; and

25 (4) the Act would amend § 843(c) to make unlawful “the placement on the internet
 26 of an advertisement that refers to or directs prospective buyers to Internet sellers of
 27 controlled substances” who are not registered to do so.

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 ³The House has not yet acted on the Bill.

Defendant Bidwell also points to proposed legislation, which was never passed, in the 108th and 109th Congresses in 2004 and 2005. Bills proposed in those years also would have specifically defined “valid prescription for controlled substance” as requiring at least one in-person medical evaluation. [Philip Bidwell’s Motion to Dismiss, Doc. No. 313, Attachment D, pp. 6-7; Attachment E, p. 5; Attachments F, and G.]. Notably, however, these bills proposed amendments to the Federal Food, Drug, and Cosmetic Act, not the CSA. Another Senate bill proposed in 2006 would have amended the CSA to prohibit the conduct which is the target of this case against the affiliates, but arguably would have made violation of the statute by internet advertisers a misdemeanor. [Attachment H, pp. 7-8.]

3. Due Process standard as applied to this case

Due process requires that a person be given fair notice as to what constitutes illegal conduct so that he may conform his conduct to the requirements of the law. United States v. Batchelder, 442 U.S. 114, 123 (1979). The “fair warning requirement” manifests itself in three ways:

First, the vagueness doctrine bars enforcement of “a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application.” ... Second, ... the canon of strict construction of criminal statutes, or rule of lenity, ensures fair warning by so resolving ambiguity in a criminal statute as to apply it only to conduct clearly covered. ... Third, although clarity at the requisite level may be supplied by judicial gloss on an otherwise uncertain statute ... due process bars courts from applying a novel construction of a criminal statute to conduct that neither the statute nor any prior judicial decision has fairly disclosed to be within its scope. ...

United States v. Lanier, 520 U.S. 259, 266 (1997).

As applied to this case, the Court finds the phrases “legitimate medical purpose” and “in the usual course of professional practice” are not so vague as to deprive Defendants of fair warning their conduct was illegal. Courts have consistently rejected the argument that the phrases contained in 21 C.F.R. § 1306.04, defining how prescriptions are to be issued, are unconstitutionally vague. United States v. Rosenberg, 515 F.2d 190, 197-98 (9th Cir. 1974) (noting the phrase had been used in statutes since 1914 and courts had shown “ease and consistency” in interpreting the phrase); United States v. Collier, 478 F.2d 268, 272 (5th Cir. 1973) (“in the usual course of professional practice” language not unconstitutionally vague); United

1 States v. DeBoer, 966 F.2d 1066, 1068-69 (6th Cir. 1992) (language of § 841(a)(1) is not void for
 2 vagueness because it clearly defines a pharmacist's responsibilities); United States v. Prejean, 429
 3 F. Supp. 2d 782, 805 (E.D. La. 2006) (rejecting defendants' argument that a lack of consensus
 4 among the medical community regarding what is considered "legitimate medical purpose"
 5 rendered statute and regulation void for vagueness); United States v. Quinones, 536 F. Supp. 2d
 6 267, 274 (E.D.N.Y. 2008) (rejecting void for vagueness argument made by operators of nearly
 7 identical internet pharmaceutical operation). Defendants have not cited to a single case finding the
 8 statute or regulation to be insufficient to give notice of what conduct is prohibited.

9 The Affiliate marketing defendants argue the statutes and regulations have heretofore been
 10 applied only in prosecuting doctors, pharmacists, or those very closely associated with those
 11 professionals. As a result, the Affiliate marketing Defendants argue they could not have known
 12 their conduct violated the criminal laws. Defendants, however, cite no persuasive authority for
 13 their argument. Courts have upheld convictions of non-practitioners for conspiring to distribute,
 14 or aiding and abetting the distribution of controlled substances based upon prescriptions issued
 15 outside the course of medical practice. United States v. Green, 511 F.2d 1062, 1070-71 (7th Cir.
 16 1975) (upholding conviction of owner of building that housed medical center and pharmacy based
 17 upon evidence defendant was fully aware the medical clinic and pharmacy were operating in a
 18 manner which was not medically justified); United States v. Hicks, 529 F.2d 841, 844 (5th Cir.
 19 1976) (finding security guard with 4th grade education could be convicted under § 841(a)(1)
 20 because "[i]t was not necessary that Hicks personally 'dispense' only that he knowingly
 21 participated in a conspiracy ... to dispense controlled substances in violation of 21 U.S.C.
 22 § 841(a)(1)); United States v. Mahar, 801 F.2d 1477, 1487 (6th Cir. 1986) (pharmacy manager);
 23 United States v. Vamos, 797 F.2d 1146, 1153 (2d Cir. 1986) (nurse/office manager). Although the
 24 government may not have previously prosecuted persons in the same position as the Affiliate
 25 marketers⁴, the application of the law to the conduct alleged in the indictment is not so novel as to
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27 ⁴The prosecutor represented to the Court at the time of the hearing that there was at least one
 28 Affiliate marketer charged in the Quinones case pending in the Eastern District of New York and
 referenced herein. After the hearing, both defense and government counsel filed letter briefs disputing
 the nature of the involvement of the individual charged in Quinones. This dispute is immaterial

1 deprive defendants of due process. The defendants had fair warning their conduct could expose
2 them to criminal liability.

3 Defendants urge the Court to look to the recently passed Senate Bill, proposing an
4 amendment to the CSA, in order to find the CSA does not currently prohibit the type of internet
5 sales of pharmaceuticals alleged in this action. However, “[t]hat Congress has considered clearer
6 legislation ... does not mean that existing laws do not apply” Quinones, 536 F. Supp. 2d at 273.
7 “[S]tatutes are construed by the courts with reference to the circumstances existing at the time of
8 the passage. The interpretation placed upon an existing statute by a subsequent group of
9 Congressmen who are promoting legislation and who are unsuccessful has no persuasive
10 significance here.” United States v. Wise, 370 U.S. 405, 411 (1962). The fact that the Senate has
11 passed a bill which would amend the CSA to explicitly prohibit the conduct at issue in this case
12 does not invalidate the government’s prosecution of defendants under the existing provisions of
13 the CSA.

14 The indictment alleges these defendants affirmatively participated in the conspiracy to
15 unlawfully distribute controlled substances. Affpower’s customers were connected to the doctors
16 and pharmacists through the Affiliate marketers’ websites. The Affiliate websites advertised
17 products and prices and then re-directed customers to an Affpower merchant website. Through the
18 merchant website, the customer made a buying decision, filled out a medical questionnaire, placed
19 an order, and gave credit card and shipping information, all before the doctors or pharmacists
20 became involved. The Court finds the statute and regulation, both as written and as interpreted by
21 judicial decisions, gave fair notice the conduct alleged in the Indictment was unlawful. The
22 government’s prosecution of the Affiliate marketers based upon their role in marketing
23 pharmaceuticals over the Internet as alleged in the Indictment is not so novel as to violate due
24 process. The Court DENIES Defendants’ motion to dismiss the Indictment.⁵

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26 because the Court finds defendants had fair warning under the statute and controlling case law.

27 ⁵In their motion, Defendants Lovin and Aronson argue the government should be barred from
28 going forward because a DEA agent inspected their pharmacy while the investigation was pending
and told them everything looked fine. In addition, the Affiliate marketing Defendants argue they were
affirmatively misled regarding the lawfulness of the Affpower enterprise by one of the Government’s

Motion to Dismiss Counts 1 and 2

The Affiliate marketer Defendants move to dismiss Counts 1 and 2 of the Indictment for failure to state a claim, arguing the indictment fails to allege an “association in fact” enterprise within the reach of RICO. Alternatively, the affiliate defendants argue they did not “participate in the operation or management of the enterprise” as required for a violation of 18 U.S.C. § 1962(c). Finally, the affiliate defendants argue the Affpower “enterprise” posed no “threat of continuing unlawful activity.”

Rule 7(c)(1) provides that an indictment must contain “a plain, concise and definite written statement of the essential facts constituting the offense charged.”

[A]n indictment is sufficient if it, first, contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and, second, enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense. ... It is generally sufficient that an indictment sets forth the offense in the words of the statute itself, as long as “those words of themselves fully, directly, and expressly, without any uncertainty or ambiguity, set forth all the elements necessary to constitute the offense intended to be punished.”

Hamling v. United States, 418 U.S. 87, 117 (1974) (quoting United States v. Carll, 105 U.S. 611, 612 (1882)) (other internal citations omitted); see also United States v. Woodruff, 50 F.3d 673, 676 (9th Cir. 1995); United States v. Ely, 142 F.3d 1113, 1120 (9th Cir. 1997).

Under Ninth Circuit authority, the sufficiency of the indictment is judged:

by whether the indictment adequately alleges the elements of the offense and fairly informs the defendant of the charge, not whether the Government can prove its case. For purposes of review, the allegations of the indictment are presumed to be true. An indictment should be: (1) read as a whole; (2) read to include facts which are necessarily implied; and (3) be construed according to common sense.

United States v. Blinder, 10 F.3d 1468, 1471 (9th Cir. 1993). These standards apply to the RICO claims alleged in the Indictment. Id. (reviewing and finding sufficiency of RICO indictment).

A review of the Indictment demonstrates the RICO counts are sufficiently pled because they allege all the essential RICO elements and provide the Defendants notice of the charges against which they must defend. For example, Paragraph 4 of the Indictment, which is expressly incorporated into Counts 1 and 2, provides:

witnesses. The Court also finds these factual assertions insufficient to justify dismissal of the Indictment.

1 The Affpower enterprise, including its leadership, membership and associates,
 2 constituted an “enterprise,” as defined by Title 18, United States Code, Section
 3 1961(4), that is, a group of individuals and entities associated in fact. The
 4 enterprise had an ascertainable structure separate and apart from the structure
 inherent in the conduct of its racketeering activity, and it constituted an ongoing
 organization whose members functioned as a continuing unit for a common purpose
 of achieving the objectives of the enterprise.

5 In addition, the introductory paragraphs to the Indictment set forth in detail the organizational
 6 structure and operation of the Affpower enterprise. These paragraphs sufficiently allege the
 7 existence of a closely associated and diverse group of individuals who coalesced indefinitely for
 8 the purpose of committing criminal activities on an ongoing basis and whose association existed
 9 and continued independently of the commission of any independent racketeering act. See Chang
 10 v. Chen, 80 F.3d 1293, 1299 (9th Cir. 1996) (establishing extent of structure an organization must
 11 have to be an enterprise under RICO).

12 The indictment also alleges Defendants participated in the conduct of the enterprise’s
 13 affairs. [Indictment, ¶¶ 6, 14, 16, 17-35.] Defendants’ motion focuses on the legal standard a
 14 court should apply to determine whether there was sufficient evidence of an individual’s
 15 participation in the enterprise’s affairs to sustain a conviction under RICO. However, the question
 16 of whether any individual Defendant’s participation in the enterprise is sufficient to sustain a
 17 conviction is separate from the question presented by this motion – whether the allegations of the
 18 indictment are sufficient to withstand dismissal. The Court finds the “participation” element of the
 19 RICO offense is sufficiently pled.

20 Finally, the concepts of “relatedness and continuity” are not elements of the RICO offense,
 21 but instead are ways of expressing RICO’s requirement of *proof* of “a pattern of racketeering
 22 activity.” United States v. Torres, 191 F.3d 799, 806 (7th Cir. 1999) (RICO indictment setting
 23 forth words of the statute without reference to the continuity requirement was sufficient).

24 Nonetheless, the indictment does allege that the Affpower enterprise was an ongoing criminal
 25 organization, established in August 2004 and continuing through June 2006 for the purpose of
 26 illegally selling controlled and non-controlled prescription drugs online to customers located
 27 throughout the United States. [Indictment, ¶¶ 1, 14, 16.] As a result, the Court DENIES
 28 Defendants’ motion to dismiss the RICO counts.

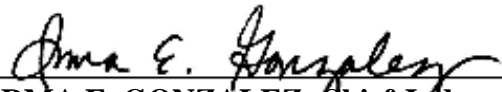
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Conclusion

For the reasons set forth herein, the Court DENIES Defendants' motions to dismiss the Indictment.

IT IS SO ORDERED.

DATED: September 29, 2008


IRMA E. GONZALEZ, Chief Judge
United States District Court